

113TH CONGRESS  
1ST SESSION

# H. R. 2090

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to permit provisional approval of fast track products.

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## IN THE HOUSE OF REPRESENTATIVES

MAY 22, 2013

Mr. GRIFFITH of Virginia (for himself, Mr. McCaul, and Mr. PETERS of California) introduced the following bill; which was referred to the Committee on Energy and Commerce

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## A BILL

To amend chapter V of the Federal Food, Drug, and Cosmetic Act to permit provisional approval of fast track products.

1       *Be it enacted by the Senate and House of Representa-  
2 tives of the United States of America in Congress assembled,*

**3 SECTION 1. SHORT TITLE.**

4       This Act may be cited as the “Patient Choice Act  
5 of 2013”.

1   **SEC. 2. PROVISIONAL APPROVAL FOR FAST TRACK PROD-**  
2                 **UCTS.**

3                 (a) IN GENERAL.—Section 506 of the Federal Food,  
4   Drug, and Cosmetic Act (21 U.S.C. 356) is amended by  
5   adding at the end the following:

6                 “(f) PROVISIONAL APPROVAL.—

7                 “(1) PROVISIONAL APPROVAL FOR ADEQUATELY  
8   SAFE FAST TRACK PRODUCTS.—

9                 “(A) IN GENERAL.—Subject to the re-  
10          quirements of this subsection, if the Secretary  
11          determines that a drug that is designated as a  
12          fast track product under this section is ade-  
13          quately safe (as such term is defined in para-  
14          graph (2)), the Secretary shall grant provisional  
15          approval and the drug may be introduced into  
16          interstate commerce on or after the date such  
17          provisional approval is granted.

18                 “(B) TREATMENT OF PROVISIONAL AP-  
19          PROVAL STATUS.—The provisional approval of a  
20          drug under subparagraph (A) shall be treated  
21          in the same manner as approval of a drug  
22          under section 505 of this Act or section 351 of  
23          the Public Health Service Act, except that such  
24          provisional approval shall be subject to the re-  
25          quirements of this section, including the fol-  
26          lowing:

1                         “(i) The requirements under para-  
2                         graph (3), including requirements related  
3                         to—

4                             “(I) informed consent; and  
5                             “(II) continued pursuit of safety  
6                         and efficacy data for purposes of  
7                         gaining approval for such drug under  
8                         section 505 of this Act or section 351  
9                         of the Public Health Service Act.

10                         “(ii) The rules under paragraphs (4)  
11                         and (5) relating to the length of the termi-  
12                         nation of the provisional approval and  
13                         withdrawal of a drug subject to provisional  
14                         approval.

15                         “(C) REQUEST FOR PROVISIONAL AP-  
16                         PROVAL.—

17                         “(i) IN GENERAL.—The sponsor of a  
18                         drug that is designated as a fast track  
19                         product under this section may request  
20                         that the Secretary grant provisional ap-  
21                         proval for such drug under subparagraph  
22                         (A).

23                         “(ii) RESPONSE TO REQUEST.—Not  
24                         later than 90 days after receiving such a  
25                         request, the Secretary shall either—

1                         “(I) grant provisional approval  
2                         for the drug under subparagraph (A);  
3                         or

4                         “(II) provide notice to the spon-  
5                         sor of the drug that such request is  
6                         denied.

7                         “(2) ADEQUATELY SAFE DEFINED.—

8                         “(A) IN GENERAL.—For purposes of this  
9                         subsection, with respect to a drug, the term  
10                         ‘adequately safe’ means that—

11                         “(i) for at least one population, the  
12                         risk of death or morbidity caused directly  
13                         by an adverse effect of the drug, as deter-  
14                         mined in one or more safety studies or  
15                         through other data that the Secretary de-  
16                         termines are sufficient, is unlikely to be  
17                         greater than the combined direct and sec-  
18                         ondary risks of death or morbidity, as es-  
19                         tablished in the literature or historical  
20                         data, of—

21                         “(I) the disease that such drug is  
22                         intended to treat; and

23                         “(II) existing therapies (includ-  
24                         ing infection) for such disease; or

1                         “(ii) the drug has had a valid mar-  
2                         keting authorization, for a period of at  
3                         least 4 years, by an authority in a country  
4                         described in section 802(b)(1)(A), or des-  
5                         ignated by the Secretary under section  
6                         802(b)(1)(B), and data adequate for the  
7                         approval of such marketing authorization  
8                         for such drug in such country have been  
9                         submitted to the Secretary.

10                         “(B) LIMITATION.—The Secretary may  
11                         not impose any requirements for purposes of  
12                         the safety studies or data under subparagraph  
13                         (A)(i) that are in addition to, or different than,  
14                         the requirements for studies to establish safety  
15                         for purposes of Phase 1 or Phase 2, as such  
16                         terms are described in subsections (a) and (b),  
17                         respectively, of section 312.21 of title 21, Code  
18                         of Federal Regulations.

19                         “(3) REQUIREMENTS.—Provisional approval of  
20                         a fast track product under this subsection shall be  
21                         subject to the following requirements:

22                         “(A) INFORMED CONSENT.—

23                         “(i) IN GENERAL.—As a condition of  
24                         provisional approval under paragraph (1),  
25                         the sponsor of a drug shall ensure that, be-

1 fore such drug is dispensed to an individual—  
2

3 “(I) the individual shall be in-  
4 formed that the drug is subject to  
5 provisional approval based on limited  
6 safety data and that the efficacy of  
7 the drug has not been proven;

8 “(II) the individual shall be in-  
9 formed of the known risks of the drug  
10 and any unknown but reasonably pre-  
11 dictable risks of the drug, including,  
12 as appropriate, potential risks of  
13 death, complications, or injury result-  
14 ing from use of the drug, and risks  
15 related to the potential ineffectiveness  
16 of the drug, including progression of  
17 the disease that may result in death  
18 or morbidity, or the potential for the  
19 drug to accelerate or exacerbate the  
20 disease process; and

21 “(III) the individual provides  
22 written informed consent acknowl-  
23 edging that individual has been pro-  
24 vided with and understands the infor-  
25 mation under subclauses (I) or (II).

1                         “(ii) REGULATIONS.—The Secretary  
2 shall issue regulations on the requirements  
3 for informed consent under clause (i).  
4 Such regulations shall be similar to the re-  
5 quirements for informed consent for  
6 human subjects under subpart B of part  
7 50 of title 21, Code of Federal Regula-  
8 tions, adjusted as appropriate for purposes  
9 of this subsection.

10                         “(B) PURSUIT OF FULL APPROVAL RE-  
11 QUIRED.—A sponsor of a drug that receives a  
12 provisional approval under paragraph (1) shall  
13 continue to diligently conduct appropriate stud-  
14 ies, after such provisional approval is granted,  
15 to—

16                         “(i) establish that the drug has an ef-  
17 fect on a clinical endpoint or on a surro-  
18 gate endpoint that is reasonably likely to  
19 predict clinical benefit; and

20                         “(ii) collect the data necessary to  
21 demonstrate that the drug is safe and ef-  
22 fective (or, in the case of a biologic, safe  
23 and potent) for purpose of obtaining ap-  
24 proval for such drug under section 505(c)

1                   of this Act or section 351 of the Public  
2                   Health Service Act.

3                 “(C) PROMOTIONAL MATERIALS.—During  
4                   the period that provisional approval under para-  
5                   graph (1) applies to a drug, the sponsor of the  
6                   drug shall submit copies of all promotional ma-  
7                   terials related to the drug at least 30 days prior  
8                   to dissemination of the materials.

9                 “(D) RISK EVALUATION AND MITIGATION  
10                  STRATEGY.—

11                 “(i) IN GENERAL.—Section 505–1  
12                   shall apply to a drug subject to provisional  
13                   approval under this subsection in the same  
14                   manner that such section applies to a drug  
15                   approved under section 505 of this Act or  
16                   section 351 of the Public Health Service  
17                   Act.

18                 “(ii) RULE OF CONSTRUCTION.—  
19                   Nothing in this subparagraph shall be con-  
20                   strued to limit the Secretary’s authority  
21                   under section 505–1 to determine if a risk  
22                   evaluation and mitigation strategy is nec-  
23                   essary.

1                 “(E) INDICATION OF USE.—The provi-  
2                 sional approval under paragraph (1) shall only  
3                 apply to the indication of use for the drug—

4                         “(i) which is related to the treatment  
5                 of the condition with respect to which such  
6                 drug was designated as a fast track prod-  
7                 uct; and

8                         “(ii) for which the drug is dem-  
9                 onstrated to be adequately safe.

10                 “(4) TERMINATION OF PROVISIONAL AP-  
11                 PROVAL.—

12                 “(A) IN GENERAL.—In the case of a drug  
13                 that is not designated under section 526, the  
14                 provisional approval of the drug under para-  
15                 graph (1) shall terminate on the earlier of the  
16                 following:

17                         “(i) The date that the drug is ap-  
18                 proved under section 505(c) of this Act or  
19                 section 351 of the Public Health Service  
20                 Act.

21                         “(ii) At the end of the 5-year period  
22                 beginning on the date on which provisional  
23                 approval was granted for such drug, ex-  
24                 cept—

1                         “(I) if the Secretary determines  
2                         that the sponsor of the drug is dili-  
3                         gently engaging in actions (including  
4                         conducting clinical trials) for the pur-  
5                         pose of seeking approval under section  
6                         505(c) of this Act or section 351 of  
7                         the Public Health Service Act (exclud-  
8                         ing provisional approval under para-  
9                         graph (1)) and the Secretary deter-  
10                         mines that the sponsor requires addi-  
11                         tional time to complete such actions  
12                         and attain such approval, the Sec-  
13                         retary may extend such period for an  
14                         appropriate length of time to allow  
15                         the sponsor to complete such actions  
16                         and attain such approval; or

17                         “(II) if the Secretary determines  
18                         that the termination of the provisional  
19                         approval is adverse to protecting or  
20                         promoting the public health, the Sec-  
21                         retary may extend such period for an  
22                         appropriate length of time to protect  
23                         or promote the public health.

24                         “(B) SPECIAL RULE FOR ORPHAN  
25                         DRUGS.—In the case of a drug designated

1           under section 526, the provisional approval of  
2           the drug under paragraph (1) shall terminate  
3           on the date that the drug is approved under  
4           section 505(c) of this Act or section 351 of the  
5           Public Health Service Act.

6           “(C) RULE OF CONSTRUCTION.—For pur-  
7           poses of this paragraph, the phrase ‘approved  
8           under section 505(c) of this Act or section 351  
9           of the Public Health Service Act’ shall not be  
10          construed to include a provisional approval  
11          under paragraph (1).

12          “(5) WITHDRAWAL.—

13           “(A) IN GENERAL.—Subsection (b)(3)  
14          shall apply to a drug subject to a provisional  
15          approval under this subsection in the same  
16          manner as such subsection applies to any fast  
17          track product.

18           “(B) ADDITIONAL WITHDRAWAL AUTHOR-  
19          ITY.—In addition to subparagraph (A), the Sec-  
20          retary may withdraw approval of a fast track  
21          product using the expedited procedures applied  
22          under subsection (b)(3) if the requirements of  
23          paragraph (3)(A) have not been met with re-  
24          spect to the drug.

## 1           “(6) IMPACT ON MARKETING EXCLUSIVITY.—

2         The rules related to marketing exclusivity under sec-  
3         tions 505(c)(3)(E), 505(j)(5)(F), 505A, and 527  
4         shall apply to a drug subject to provisional approval  
5         under this subsection in the same manner that such  
6         rules apply to drugs approved under section 505 of  
7         this Act or section 351 of the Public Health Service  
8         Act, except that the period of provisional approval  
9         under this subsection for a drug shall be an addition  
10        to the applicable period of marketing exclusivity for  
11        such drug.”.

## 12           (b) MISBRANDING FOR MARKETING OF TERMINATED

13 DRUG.—Section 502 of the Federal Food, Drug, and Cos-  
14 metic Act is amended by adding at the end the following:

15        “(bb) If it is a drug that is introduced or delivered  
16 for introduction into interstate commerce after the date  
17 of the termination of the provisional approval for such  
18 drug under section 506(f), unless, on or before the date  
19 such drug is so introduced or delivered, such drug is ap-  
20 proved under section 505(c) of this Act or section 351 of  
21 the Public Health Service Act.”.

22           (c) CONFORMING AMENDMENTS.—The chapter V of  
23 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.  
24 351) is further amended—

1                         (1) in section 502(a), by inserting “(or an indica-  
2                         tion subject to a provisional approval under sec-  
3                         tion 506(f))” after “an indication approved under  
4                         section 505 or under section 351(a) of the Public  
5                         Health Service Act”;

6                         (2) in section 506A—

7                             (A) in subsection (a), by inserting “(or a  
8                         provisional approval under section 506(f))”  
9                         after “a license under section 351 of the Public  
10                         Health Service Act”; and

11                         (B) by adding at the end the following:

12                         “(e) SPECIAL RULE FOR DRUGS SUBJECT TO PROVI-  
13                         SIONAL APPROVAL.—In the case of a drug subject to a  
14                         provisional approval under section 506(f), any reference  
15                         to safety and efficacy under this section shall be treated  
16                         as a reference to adequate safety, as such term is defined  
17                         for purposes of such section 506(f).”;

18                         (3) in section 506B(a), by adding at the end  
19                         the following:

20                         “(3) SPECIAL RULE FOR PROVISIONAL AP-  
21                         PROVAL.—A sponsor of a drug that is subject to a  
22                         provisional approval under section 506(f) shall sub-  
23                         mit the reports required under this section on the  
24                         studies conducted on such drug that are described in  
25                         section 506(f)(3)(B). For purposes of this section,

1 such reports shall be treated as reports on post-  
2 marketing studies described in paragraph (1).”;  
3 (4) in section 551(b)(1)(A) by inserting “(or a  
4 provisional approval under section 506(f))” after  
5 “Public Health Service Act”.

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